

REMARKS

Claims 1-22 are amended in the present amendment. No claims have been cancelled. Claims 23-28 are newly presented.

No new matter is added by way of the amendments.

Claims 1-22 were examined and stand rejected. Claim 22 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 1, 20, 21 and 22 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Brown, U.S. 6,168,616 (hereafter "Brown"). Claims 1, 15, 16, and 22 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Marin et al., U.S. 5,443,477 (hereafter "Marin"). Claim 2 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Brown in view of Glukhovsky et al., U.S. 6,986,738 (hereafter "Glukhovsky"). Claims 3-14 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Brown in view of Glukhovsky, and further in view of "a matter of obvious design choice." Claims 17-19 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Brown in view of Mikus et al., U.S. 20020151967 (hereafter "Mikus").

These grounds of rejection are respectively traversed.

As discussed during the Interview of June 19, 2006, with this response, Applicants submit a Terminal Disclaimer over U.S. Patent Application 10/651,840.

The Rejection of Claim 22 under 35 U.S.C. §112

Claim 22 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Claim 22 has been amended to overcome this ground of rejection. Applicants respectfully submit that Claim 22 is not indefinite, and that the rejection of Claim 22 under 35 U.S.C. §112, second paragraph is overcome.

The Rejections of Claims 1, 20, 21 and 22 under 35 U.S.C. §102(b)

Claims 1, 20, 21 and 22 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Brown, U.S. 6,168,616 (hereafter "Brown").

Anticipation under 35 U.S.C. § 102 requires that "every element of the claimed invention be identically shown in a single reference." (*In re Bond*, 910 F.2d 831,832 (Fed. Cir. 1990).

In one embodiment of the present invention, as set forth in claim 1, a system is provided for positioning an implantable device for an anatomic orifice or lumen. The implantable device has a surface that comes in direct contact with the anatomic orifice or lumen and that substantially defines a plane. An implantable device has an adjustable member configured to adjust the dimensions of the implantable device. The adjustable member is configured to be coupled to an adjustment tool that provides adjustment before, during or after the anatomic orifice or lumen resumes near-normal to normal physiologic function. During adjustment, the adjustment tool is positioned non-planar relative to the plane defined by the surface of the implantable device. An apparatus includes a first shaft has proximal and distal ends. A second shaft has proximal and distal ends and being slidably received within the first shaft. A plurality of arms are provided. Each arm has a distal end deflectably mounted to the distal end of the second shaft at least a port. At least one deflection device is configured to deflect a proximal end of each of the plurality of arms away from the second shaft when relative movement between the first and second shafts is effected. A device is provided that holds the implantable device to the proximal ends of the arms

However, in contrast, Brown discusses a stent delivery system that carries a stent, particularly a triple A stent graft, to be delivered to a target site. In Brown, the delivery system is slid into a desired location in a vessel. The stent is

delivered and expanded by longitudinal compression. The surface of the vessel and the surface of the stent share the same longitudinal axis, along which the compression occurs which expands the stent. Brown does not have a system that includes an implantable device with an adjustable member configured to adjust the dimensions of the implantable device, the implantable device having a surface that substantially defines a plane, and having an adjustment tool configured to be positioned in a non-planar orientation relative to that plane. As set forth in claim 1, the adjustable member is configured to be coupled to an adjustment tool that provides adjustment before, during or after the anatomic orifice or lumen resumes near-normal to normal physiologic function. When coupled to the adjustable member, the adjustment tool is positioned non-planar relative to the plane substantially defined by the surface of the implantable device that comes in direct contact with the anatomic orifice or lumen.

Brown lacking elements of the claimed invention, Applicants respectfully submit that claims 1, 20, 21 and 22 are not anticipated by the cited reference and recite allowable subject matter. Accordingly, Applicants believe the rejections of claims 1, 20, 21 and 22 under 35 U.S.C. § 102(b) to be overcome.

The Rejections of Claims 1, 15, 16 and 22 under 35 U.S.C. §102(b)

Claims 1, 15, 16, and 22 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Marin et al., U.S. 5,443,477 (hereafter "Marin").

Marin et al. is also a graft stent delivery system. Like Brown, Marin et al. expands a stent by longitudinal compression, and does not have an implantable device with an adjustable member configured to adjust the dimensions of the implantable device. The adjustable member of embodiments of the present invention is configured to be coupled to an adjustment tool that provides adjustment before, during or after the anatomic orifice or lumen resumes near

normal to normal physiologic function. The adjustment tool is positioned non-planar relative to the plane of the implantable device during adjustment.

Marin lacking elements of the claimed invention, Applicants respectfully submit that claims 1, 15, 16, and 22 are not anticipated by the cited reference and recite allowable subject matter. Accordingly, Applicants believe the rejections of claims 1, 15, 16, and 22 under 35 U.S.C. § 102(b) to be overcome.

The Rejection of Claim 2 under 35 U.S.C. §103(a)

Claim 2 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Brown in view of Glukhovsky et al., U.S. 6,986,738 (hereafter "Glukhovsky").

In order to establish a prima facie case of obviousness, there must be 1) some suggestion or motivation in the art or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Glukhovsky et al. provides a system for maneuvering a sensing device in vivo. A sensing device is positioned at a distal end of a tube that can deliver tools and the like to a target site. Glukhovsky et al. also fails to provide an implantable device as set forth in claim 1. As discussed above, Brown fails to provide elements of the present invention; Glukhovsky et al. fails to provide the missing elements. Thus, the cited references do not disclose all the elements of the claimed invention.

Moreover, the cited references provide no motivation or suggestion to provide the missing elements, and, lacking disclosure of elements of the invention, fail to provide any reasonable expectation of success.

Accordingly, the cited references lacking elements of the claimed invention, providing no motivation to combine the cited references to provide the claimed invention, nor any reasonable expectation of success were the references to be so combined, applicants respectfully submit that claim 2 is not made obvious by the cited references.

The Rejections of Claims 3-14 under 35 U.S.C. §103(a)

Claims 3-14 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Brown in view of Glukhovsky, and further in view of “a matter of obvious design choice.”

However, as discussed above, Brown in view of Glukhovsky lacks elements of the claimed invention. For example, Brown lacks disclosure of a system that includes an implantable device with an adjustable member configured to adjust the dimensions of the implantable device that is oriented substantially along a plane defined by an anatomic orifice or lumen. Glukhovsky does not make up for this lack.

Such missing elements are not provided by an “obvious design choice.”

Moreover, the cited references, including “an obvious design choice,” provide no motivation or suggestion to provide the missing elements, and, lacking disclosure of elements of the invention, fail to provide any reasonable expectation of success.

Accordingly, since the combined cited references do not disclose all the elements of the claimed invention, provide no motivation to combine the cited references to provide the claimed invention, nor any reasonable expectation of success were the references to be so combined, applicants respectfully submit that claims 3-14 are not made obvious by the cited references.

The Rejections of Claims 17-19 under 35 U.S.C. §103(a)

Claim 17-19 stand rejected under §103(a) as obvious over Brown in view of Mikus (US 20020151967).

Mikus et al. discloses a stent system for the delivery of a device to the prostate gland. The Mikus system also does not have an implantable device as set forth in claim 1. As discussed above, Brown also lacks at least this element.

Moreover, neither Mikus nor Brown provide any motivation or suggestion to provide the missing elements, and, lacking disclosure of elements of the invention, fail to provide any reasonable expectation of success.

Accordingly, since Mikus and Brown fail to disclose an implantable device as set forth in claim 1, and fail to disclose other elements of the claimed invention; provide no motivation to combine the cited references to provide the claimed invention; and fail to provide any reasonable expectation of success were the references to be so combined, applicants respectfully submit that claims 17-19 are not made obvious by the cited references.

CONCLUSION

It is submitted that the present application is in form for examination, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **08-1641** (Docket No. 42749-0012).

Respectfully submitted,

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Date: August 11, 2006



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